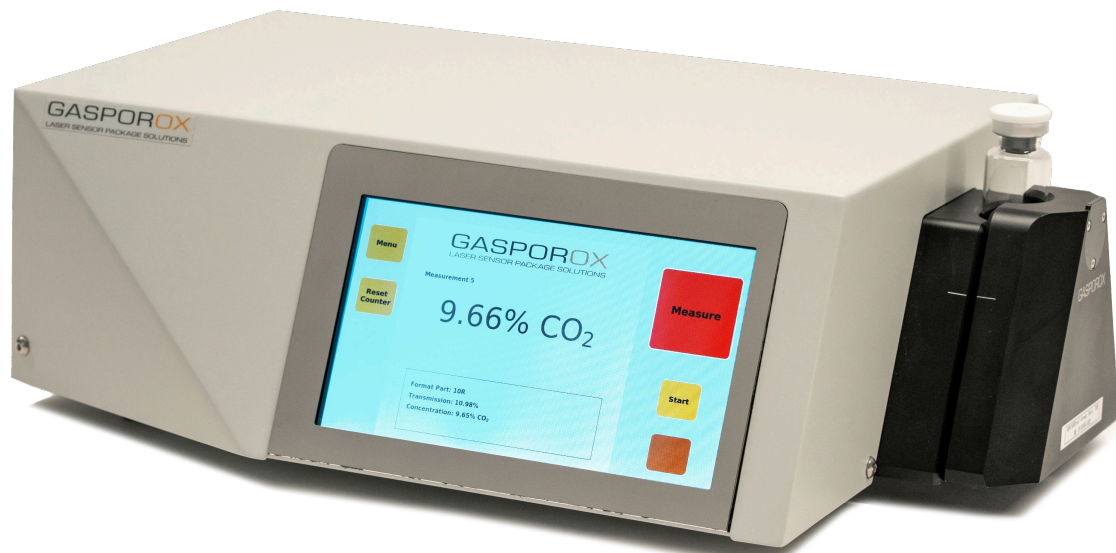


CO₂ Bombing

How the GPX1500 Vial and CO₂ bombing provide a modern alternative to dye ingress testing.



Executive Summary

In pharmaceutical and biotech manufacturing and development, ensuring container closure integrity (CCI) is critical for product sterility and regulatory compliance. The traditional dye ingress test remains widely used but at its' core it has multiple flaws as it is probabilistic, destructive, and subjective.

Using CO₂ bombing in combination with the Gasporox GPX1500 Vial CO₂ instrument, manufacturers can now perform deterministic leak detection using CO₂ as a tracer gas. This approach offers non-destructive, quantitative, and regulatory-compliant CCI verification, aligning with USP <1207> and Annex 1 demands and expectations.

This case illustrates how pharmaceutical QC teams can transition from conventional dye ingress to a data-driven, repeatable CO₂-based method that improves both compliance and efficiency.

Industry Context

- **Industry:** Injectable pharmaceuticals
- **Typical Applications:** Sterile vial integrity testing, closure validation, and stability studies
- **Common Challenge:** Transitioning from destructive, manual CCI tests to deterministic solutions

“Dye ingress has served the industry for decades, but deterministic methods now provide the accuracy and reproducibility regulators expect.”

The Challenge

Manufacturers and developers of pharmaceuticals and biotech face increasing pressure to adopt deterministic CCIT methods that deliver objective and traceable results.

Traditional dye ingress testing presents multiple limitations:

- **Destructive:** tested units cannot be released
- **Operator-dependent:** high subjectivity and risk of error
- **Limited sensitivity:** small leaks often undetected
- **Non-quantitative:** pass/fail results only

To meet Annex 1 and USP <1207> requirements, a deterministic, non-destructive alternative was required that could match or exceed dye ingress sensitivity while maintaining practical laboratory workflows.

The Solution

The GPX1500 Vial CO₂ uses laser-based tunable diode laser absorption spectroscopy (TDLAS) to measure CO₂ concentration in the vial headspace with high precision. When combined with CO₂ bombing, this enables sensitive, repeatable leak detection using CO₂ as a tracer gas.

How it works:

1. Vials are placed in a CO₂-rich chamber for a defined period.
2. Any microleak allows CO₂ to enter through the defect.
3. The GPX1500 Vial measures the CO₂ levels in the headspace, an increase indicates a leak path.

Key implementation benefits:

- Deterministic and quantitative results
- Fully non-destructive and repeatable
- No consumables beyond CO₂
- Simple correlation to existing dye ingress thresholds

This method bridges the gap between traditional probabilistic testing and modern deterministic CCIT requirements.

Key Takeaways

- CO₂ bombing with GPX1500 Vial enables deterministic leak detection using a tracer gas approach
- Offers a non-destructive replacement for dye ingress with quantitative verification
- Fully supports Annex 1 and USP <1207> compliance requirements
- Scalable from laboratory validation to inline or automated QC processes

Interested in upgrading from dye ingress to deterministic CCIT?

Learn how Gasporox GPX1500 Vial CO₂ with CO₂ tracer gas testing can help you achieve compliant, efficient, and non-destructive leak detection.

Contact Gasporox to discuss your CCIT strategy.

sales@gasporox.se